K120278

510(k) SUMMARY

AUG 10 2012

WIRELESS IMAGE TRANSMITTER UNIT UWIT-Y0001

January 25, 2012

1 General Information

- Applicant:

OLYMPUS MEDICAL SYSTEMS CORP.
2951 Ishikawa-cho, Hachioji-shi, Tokyo, Japan 192-8507
Establishment Registration No: 8010047

- Official Correspondent:

Stacy Abbatiello Kluesner, M.S., RAC
Regulatory Affairs & Quality Assurance
Olympus America Inc.
3500 Corporate Parkway
PO Box 610
Center Valley, PA 18034-0610, USA
Phone: 484-896-5405
FAX: 484-896-7128
Email: stacy.kluesner@olympus.com

- Manufacturer:

SHIRAKAWA OLYMPUS CO., LTD.
3-1, Aza-Ookamiyama, Ooaza-Odakura, Nishigo-mura,
Nishishirakawa-gun, Fukushima, Japan 961-8061
Establishment Registration No: 3002808148

2 Device Identification

- Device Trade Name: WIRELESS IMAGE TRANSMITTER UNIT UWIT-Y0001
- Common Name: Wireless Image Transmitter Unit
- Regulation Number: 21 CFR 876.1500
- Regulation Name: Endoscope and accessories
- Regulatory Class: II
- Classification Panel: Gastroenterology/Urology
- Product Code: GCJ

3 Predicate Device Information

- Device Name: ZeroWire® Duo Wireless HD Video Transfer System

P 1/3

- Common Name: UWB Wireless Device
- Manufacturer: NDS Surgical Imaging, LLC
  5750 Hellyer Avenue
  San Jose, CA 95138
  USA
- 510(k) No. K100195

4 Device Description

The WIRELESS IMAGE TRANSMITTER UNIT UWIT-Y0001 consists of a Wireless Transmitter UWIT-Y0001-TX, a Wireless Receiver UWIT-Y0001-RX and accessories. The UWIT-Y0001-TX transmits endoscopic image over radio frequency signal and the UWIT-Y0001-RX receives it. The endoscopic image signal output by the Video System Center is sent to the UWIT-Y0001-TX. Then, the UWIT-Y0001-TX converts the endoscopic image signal to the radio frequency signal and transmits it to the UWIT-Y0001-RX. The UWIT-Y0001-RX converts the radio frequency signal received from the UWIT-Y0001-TX to endoscopic image signal and sends it to the video monitor

5 Indications for Use

The Olympus Wireless Image Transmitter Unit UWIT-Y0001 is a paired transmitter and receiver, intended for delivery of video signals over a radio-frequency link to a video display during endoscopic and general surgical procedures. The Olympus UWIT-Y0001 is a non-sterile reusable device not intended for use in the sterile field. It is intended for use by qualified physicians having complete knowledge of these surgical procedures.

6 Comparison of Technological Characteristics

The WIRELESS IMAGE TRANSMITTER UNIT UWIT-Y0001 is basically identical to the predicate device in intended use, and similar in specifications.

Compared to the predicate device, the subject device has the same intended use. There are differences in radio-frequency band, number of frequency channel, and compression technology, video input selection. However, these differences are considered as minor.

7 Substantially Equivalence Discussion

The WIRELESS IMAGE TRANSMITTER UNIT UWIT-Y0001 has the same intended use with the predicate device. Both the subject device and predicate device are a paired transmitter and receiver intended for the wireless delivery of video signals over radio frequency during endoscopic procedures. Both systems consist of a single transmitter that is linked to single receiver. Both the predicate device and the subject device conform to the relative electrical

safety standards, EMC standards, FCC part 15 standards and were evaluated for safe use in non-clinical setting testing. The main differences between the subject and predicate devices is the radio frequency band utilized.. Therefore, the subject device is considered as substantially equivalent to the predicate device.

8 Summary of Non-clinical Testing

Evaluation testing demonstrated that the WIRELESS IMAGE TRANSMITTER UNIT UWIT-Y0001 can perform as intended and transmit HD video signals in expected use environment without interfering other devices.

Basic safety and performance testing was performed in accordance with IEC 60601-1, IEC 60601-1-1, and IEC 60601-1-2. In addition, verification was conducted to evaluate the mechanical and functional performance.

Risk analysis was carried out in accordance with established in-house acceptance criteria based on ISO 14971:2007. The design verifications tests and their acceptance criteria were identified and performed as a result of this risk analysis assessment.

The software validation activities were performed in accordance with the FDA Guidance, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The device software is considered a "Minor Level of Concern."

As the UWIT-Y0001 is considered to be an intentional radiator prescribed under Federal Communications Commission (FCC) 47 CFR Part 15 – Radio Frequency Devices, Subject C – Intentional Radiators, it has been evaluated to verify compliance with this regulation.

The following standards have been applied to the WIRELESS IMAGE TRANSMITTER UNIT UWIT-Y0001 :

- IEC 60601-1: 1988, Amendment 1: 1991, Amendment 2: 1995
- IEC 60601-1-1: 2000
- IEC 60601-1-2: 2007
- ISO 14971: 2007

9 Conclusion

When compared to the predicate device, the WIRELESS IMAGE TRANSMITTER UNIT UWIT-Y0001 does not incorporate any significant changes in intended use, method of operation, or design that could affect the safety or effectiveness of the device. Therefore the WIRELESS IMAGE TRANSMITTER UNIT UWIT-Y0001 is substantially equivalent to the identified predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

AUG 10 2012

Olympus Medical Systems Corporation
% Olympus America Incorporation
Ms. Sheri Musgnung
3500 Corporate Parkway
P.O. Box 610
Center Valley, Pennsylvania 18034-0610

Re: K120278
Trade/Device Name: WIRELESS IMAGE TRANSMITTER UNIT UWIT-Y0001
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated: July 25, 2012
Received: July 26, 2012

Dear Ms. Musgnung:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K120278

Device Name: WIRELESS IMAGE TRANSMITTER UNIT UWIT-Y0001

Indications For Use:

The Olympus Wireless Image Transmitter Unit UWIT-Y0001 is a paired transmitter and receiver, intended for delivery of video signals over a radio-frequency link to a video display during endoscopic and general surgical procedures. The Olympus UWIT-Y0001 is a non-sterile reusable device not intended for use in the sterile field. It is intended for use by qualified physicians having complete knowledge of these surgical procedures.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K120278